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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,750	01/03/2005	Yoichi Iimura	0425-1138PUS1	6756

2292 7590 08/07/2008  
BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER
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CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

NOTIFICATION DATE	DELIVERY MODE
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08/07/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/500,750	<b>Applicant(s)</b> IIMURA ET AL.	
	<b>Examiner</b> Celia Chang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15-20, 22-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 15-20, 22-25 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/27/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Amendment and response filed by applicants dated April 25, 2008 have been entered and considered carefully.

Claims 13-14, 21, 26 and 28 have been canceled. Claims 1-10, 16-17, 25 and 27 stayed withdrawn.

Claims 15, 18-20 and 22-23 are withdrawn from consideration being drawn to the non-elected invention by original presentation. Please note that, claims 18-20, 22-24 were originally presented as "composition" claims but now being switched to method of treatment claims. Method of treatment claims are restrictable, thus, are withdrawn by original presentation.

Claims 11-12 are pending.

2. The rejection of claims 13-15, 18, 21 and 23 is moot in view of the cancellation of claims 13-14 and 21 and amendments to claims 15, 18 and 23.

3. The rejection of claims 18-24 under 35 USC 112 first paragraph would be applicable to the method claims were they intended to be rejoined with the elected compounds since only claims free of 112 issues can be rejoined. There is no nexus that the compounds being exclusively sigma receptor active would have efficacy in such diversity of CNS disorders which have not been known to have commonality in etiology or symptoms.

4. The rejection of claims 11-12 under 35 USC 112 first paragraph with respect to the scope encompassing "hydrate" is dropped in view of the deletion of the term.

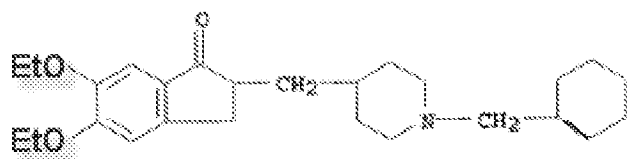
5. The rejections of claims 11-15, 18-24 under 35 USC 103(a) over US 4,895,841 in view of Iimura US 6,677,330 or Iimura '330 in view of Sugimoto '841 or further in view of Kato are maintained and are applicable to the currently amended pending claims 11-12 for reason of record.

Initially, applicants' attention is drawn to that for the rejection of the compounds of claims 11-12, the Kato reference is not required. The Sugimoto '841 and Iimur '330 are

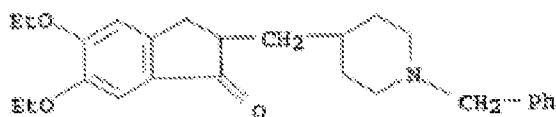
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analogous art and combination is proper. Many species has been delineated and provided to applicants. The particular picking from one compound and choosing the modification suggested in another proven compound has been clearly delineated in the previous office action. The teaching, suggestion and motivation have been clearly delineated by registry number, compound structure such as:

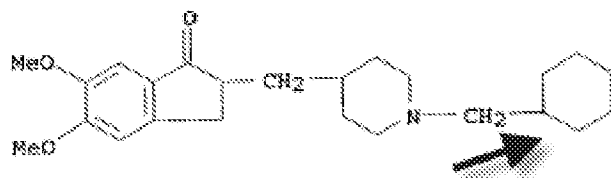
Compound 13 of claim is:



Which is modification of compound RN 120013-58-3 :



With the attribute of the right hand substitution demonstrated in the same reference and named by CAS as RN 120013-98-1:



The numerous examples were delineated which was not an exhausted listing of all the compounds. The per ponderous of examples with structure similarity which generically taught can be modified by another exemplified structurally similar species is prima facie obvious since the generic disclosure of the reference fully embraced the instant claimed compounds and with the explicit teaching and suggestion of the clearly guided examples, one having ordinary skill was in possession of the prior art generic scope and motivated to make and use any of the generically embraced compounds including the instant compounds.

The argument with respect to Tako does not affect the prima facie obviousness rendered by the references with respect to the compounds. The Tako reference clearly stated that TAK-147 and donepezil both showed high affinity for sigma receptor not just TAK-147 (see line 5

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abstract). Donepezil is the proviso compound of the instant claims, thus, structural analogous to the instant claims. Structurally similar compounds are expected to have similar activity, i.e. both AcCh esterase and sigma receptor affinity. Applicants provided no factual evidence that why the structurally analogous compounds would not also have similar biological activity being both AcCh esterase inhibitor and sigma affinity. Arguments with respect to different utility must be supported by factual evidence. Mere arguments by attorney provided little probative value. In re Hoch 166 USPQ406; In re Payne 203 USPQ 247.

**6. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**7.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*July 31, 2008*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*